

REMARKS

The Examiner's withdrawal of the finality of the previous Office Action under 37 CFR 1.114 is appreciated.

The Examiner has reminded the Applicant of the election of Figure 2 in a paper filed October 1, 2004. The Applicants respectfully request the Examiner to shift the election to Figure 3 in accordance with MPEP 819.01. The Applicants submit that no additional work or expense is necessitated by this shift and the shift reduces work by simplifying the issues. Specifically, the Examiner has already searched and issued an Office Action on the basis of pending claims 29-34 which read on Figure 3 and not Figure 2. Original claims 16-17 explicitly reading on Figure 2 have been cancelled. This shift will reduce work by eliminating the need for filing a continuation patent application.

The disclosure has been objected to by the Examiner in view of the Applicants use of means-plus function language to define the Applicants invention and the Examiner has required the Applicant to amend the specification to explicitly state, with reference to terms and phrases of the claimed elements, structure, materials and acts perform the function recited in the claimed elements.

In response thereto, the Applicants have amended the specification on page 5 and 8 to identify the structure representing the means for modulating release kinetics of the oxygenated fluorocarbon solution from the substrate. Specifically, on page 8 the profusion fluid lumen (15) is designed and provides means for allowing injection of

therapeutic liquids or drugs with temperatures between 0° and 50° Centigrade to modify the release kinetics of the oxygen carrier from the substrate.

The Examiner has objected to the drawings under 37 CFR 1.83(a) as not showing every feature of the invention as specified in the claims.

In response thereto, the Applicants submit that Figure 3 shows the profusion fluid lumen (15) as described in the specification which allows injection of therapeutic liquids or drugs with temperatures between 0° and 50° Centigrade to modify the release kinetics of the oxygen carrier from the substrate. Accordingly, the Applicants submit that new or corrected drawings are unnecessary as the claimed elements have been shown in the originally filed application.

Claims 29-32 have been objected to by the Examiner with regard to the sixth paragraph, means-plus-function language. The Applicants submit that this objection is overcome by the current amendment to the specification which correlates the means plus function and structure of the means plus function in the specification in claims.

Claims 29-30, 33-44 have been rejected by the Examiner under 35 USC 102(b) as being anticipated by U.S. 5,084,011 to Grady. In this rejection, the Examiner states that Grady teaches a method comprising the steps of oxygenation of the blood or tissue with a catheter which reduces the oxygenated fluorocarbon solution and changing the temperature of the solution to a temperature between 0° and 4° Celsius by refrigeration unit 60 and exposing device to that fluid. The

Examiner considers as a substrate to be the catheter, syringe, or cannula.

It is well known that anticipation is established only when a single prior art reference discloses, expressly or under principles of inherency, each and every element of the claimed invention. RCA Corp. v. Applied Digital Data Systems, Inc., 221 USPQ 385 (Fed. Cir. 1994).

Further, the Examiner must identify wherein each and every facet of the claimed invention is disclosed in the applied reference. *Ex Parte Levy*, 17 USPQ 2d 1461 (USPTO BPAI 1990).

In addition, the Applicants submit that anticipation must meet strict standards, and unless all of the same elements are found in exactly the same situation and united in the same way to form identical function in a single prior art reference, there is no anticipation. Tights, Inc. v. Acme-McCary Corporation, et al., 1991 USPQ 305 (CAFC 1996).

With this criteria in mind, the Applicants submit that the Grady reference is totally silent with regard to the presence of an elutable oxygenated fluorocarbon solution which is incorporated into a substrate.

A thorough reading of Grady reveals that the only mention of "fluorocarbon" is in relation to the prior art reporting an infrent breathing fluorocarbon liquid which was oxygenated with pure oxygen. See column 2, lines 40-51 of Grady.

Accordingly, there is no teaching of an elutable oxygenated fluorocarbon solution incorporated into a substrate.

With regards to means for modulating release kinetics of the oxygenated fluorocarbon solution from this substrate as set forth in independent claim 29, the only teaching in Grady is the use of a decreased temperature to maximally dissolve gaseous oxygen into liquids. See the abstract and column 3, beginning at line 13 under the summary of the invention. The refrigeration unit 60 can be activated to decrease the temperature of the gas and liquid solution to approximately 4° Centigrade in order to increase the solubility of oxygen. See column 6, lines 31-54.

Accordingly, the Grady reference teaches opposite that to the structure and function of the present invention which provides for means for modulating release kinetics of the oxygenated fluorocarbon solution from the substrate rather than utilizing temperature to maximally dissolve the gaseous oxygen into liquids.

Thus, in view of the lack of teaching of structure, similar to that claimed which functions in a manner resulting in the modulation of release kinetics of oxygenated fluorocarbon solution, a rejection under 35 USC 102(b) is not sustainable and the Examiner is respectfully requested to withdraw the rejection of claims 29-30, and 33-34 under 35 USC 102(b) on the basis of the Grady reference.

The Examiner has rejected claims 29-34 under 35 USC 103(a) as being unpatentable over U.S. 6,146,358 to Rowe in view of U.S. 5,334,142 to Paradis.

In this rejection, the Examiner states that Rowe teaches a balloon having a substrate/control release carrier on the surface which incorporates a therapeutic agent to be delivered to the internal tissue of the patient.

The Examiner states that the means for modulating and exposing is considered to be within the inflation lumen of the catheter or wall or reservoir. As best understood by the Examiner the means of Rowe is able to perform the function of the means that the Applicant has claimed. That is, the Examiner has stated that the structure allows fluid to come into contact with the substrate coating/wall which is to be considered equivalent to the structure to the balloon catheter of the Applicant. The Examiner also has stated that it is well known that the temperature at which to deliver into a patient would be one of the bodies temperature which are between 0° and 50° Celsius.

The Examiner recognizes that Rowe is silent to the therapeutic agent to be an elutable oxygenated fluorocarbon solution. Therefore, the Examiner looks to Paradis for a disclosure of the delivery of oxygen carrying fluid (fluorocarbon) for infusion. The Examiner further states that Paradis discloses that any agent that is demonstrated as effective when administrated intravenously may be more effective when administered to the heart by the balloon catheter. The Examiner then concludes it would have been obvious to one of ordinary skill in the art at the time the

invention was made to substitute the therapeutic agent of Rowe with the oxygenated fluorocarbon solution as disclosed by Paradis as a substitution of different therapeutic agents for treatment with a balloon catheter.

The Applicants submit that the Examiner has not made out a *prima facie* case of obviousness under 35 USC 103.

In accordance with the CCPA in *In re Lintner*, 173 USPQ 560, 562, the court stated: "In determining the propriety of the Office Action case for obviousness in the first instance, it is necessary to ascertain whether or not the reference teachings would appear to be sufficient to one of ordinary skill in the relevant art having the references before him to make the proposed substitution, notion or other modification."

As broadly stated, the criteria for finding obviousness under 35 USC 103 goes to the sufficiency of the reference teachings to justify the conclusion that the proposed modification is a reasonable and logical reconstruction of what a person having ordinary skill in the art would have found obvious to do at the time the invention was made. The court has held in *In re Regel*, Buchel, and Plempel, 188 USPQ 136 (CCPA 1975) that there must be some logical reason apparent from positive, concrete evidence of record would justify as a combination of primary and secondary references.

The Applicants would like to point out that the references relied on by the Examiner, namely Rowe and Paradis are totally silent as to teaching of an elutable oxygenated fluorocarbon solution incorporated into a substance and

further means for modulating the release kinetics of the oxygenated fluorocarbon solution from the substrate through the use of temperature.

Apparently, the Examiner recognizes that the references are totally silent with regard to temperature and therefore concludes that it is well known that the temperature at which to deliver into a patient would be one of the body's temperature which is between 0° and 50° Celsius. While this may be true, the Examiner has provided no factual support.

Nonetheless, merely introducing something into the body at body temperature does not provide support for a suggestion or teaching of a means for modulating the release kinetics of oxygenated fluorocarbon solution from a substrate as presently claimed. There is simply no teaching in the references cited by the Examiner for modulating release kinetics of oxygenated fluorocarbon solution from a substrate.

Accordingly, the Applicants submit that the Examiner has not made a *prima facie* case of obviousness and respectfully requests the withdrawal of the rejection of claims 29-34 under 35 USC 103(a) on the basis of the Rowe and Paradis references.

In view of the arguments hereinabove set forth and amendment to the claims and specification, it is submitted that each of the claims now in the application define patentable subject matter not anticipated by the art of record and not obvious to one skilled in this field who is aware of the references of record. Reconsideration and allowance are respectfully requested.

A check in the amount of \$60 is enclosed herewith for a one-month extension of time for responding to the outstanding Office Action.

Respectfully submitted,



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